

REMARKS

Amendment summary

Claim 22 is canceled.

No new matter is added by this Amendment, and Applicant respectfully requests entry of the Amendment.

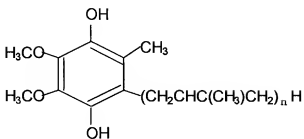
Status of the claims

Claims 10 and 12 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 03/032968. In addition, claims 10-11 and 22 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO '968 in view of Sokol (U.S. Patent No. 6,069,167).

Response to § 102 rejection based on WO '968

Claims 10 and 12 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO '968. As a preliminary matter, Applicant believes that there is a typographical error in this rejection, as claim 12 was previously canceled, and is not pending. Regardless, Applicant respectfully traverses the rejection on the grounds that, contrary to the position set forth in the Office Action, WO '968 does not disclose to a person having ordinary skill in the art that GPT or GOT activities are reduced in blood.

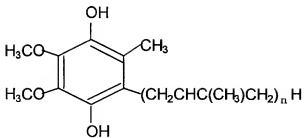
Claim 10 recites a method for protecting liver functions of a mammal, which reduces an increase in GPT or GOT activity in blood, and which comprises administering to a mammal a composition for protecting liver functions. The composition comprises reduced coenzyme Q represented by formula (1):



(1)

In formula (1), n represents an integer in the range of 1 to 12.

Although it is unclear whether claim 11 is included in this rejection, Applicant notes that claim 11 recites a method for protecting liver functions of a mammal, which reduces an increase in GPT or GOT activity in blood, and which comprises orally administering a composition for protecting liver functions. The composition comprises reduced coenzyme Q represented by formula (1):



(1)

In formula (1), n represents an integer in the range of 1 to 12.

W0 '968 teaches that an oral administration of a composition containing oxidized coenzyme Q₁₀ or reduced coenzyme Q₁₀ to SD rats reduces urinary 8OH-dG level (Example 1 of

WO '968), which is an oxidative stress marker. WO '968 further teaches a relationship between oxidative stress and many diseases, including hepatic cirrhosis (see WO '968, at 1:18-25).

However, WO '968 does not teach that reduced coenzyme Q₁₀ is effective for the protection of liver functions, much less teach that it is effective for a reduction of an increase in GPT or GOT activity in blood.

Applicant notes that generally, diseases and symptoms thereof are caused by a complex mixture of many factors. Merely getting rid of one factor does not necessarily remedy a disease or even alleviate the symptom. Prevention of a disease and improvement of a symptom resulting from the disease are not necessarily associated with each other. Actually, it is known that physiological symptoms such as an increase in GPT or GOT activity in blood are not observed often at an initial stage of hepatic cirrhosis and that the GPT or GOT activity returns to a normal level at a late stage.

WO '968 teaches that oxidized coenzyme Q₁₀ or reduced coenzyme Q₁₀, which reduces an oxidative stress marker, may prevent occurrence or worsening of diseases such as hepatic cirrhosis. Contrary to the position set forth in the Office Action, there are no findings in WO '968 teaching a person having ordinary skill in the art that reduction of oxidative stress or prevention of occurrence or hepatic cirrhosis necessarily or inherently prevents an increase in GPT or GOT activity in blood. Accordingly, WO '968 does not inherently disclose or suggest the presently claimed invention, namely a method for protecting liver functions of a mammal which reduces an increase in GPT or GOT activity in blood comprising administering a composition comprising reduced coenzyme Q.

Applicant therefore respectfully requests the reconsideration and withdrawal of this § 102 rejection.

Response to § 103 rejection based on WO '968 in view of Sokol

Claims 10-11 and 22 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO '968 in view of Sokol. Applicant respectfully traverses on the grounds that as of the filing date of the present application, it was unpredictable that a compound which reduces oxidative stress would be effective for the protection of liver functions and reduction of an increase in GPT or GOT activity in blood.

As a good example of the unpredictability, Radicut, which is referred to in WO '968 (see page 2 of the translation), is a drug which has an antioxidant activity and reduces oxidative stress. Applicant attaches documents to the present Amendment (BBC NEWS and page 88, left column of Higashi et al.) which show that serious side effects, including liver dysfunction, have been reported.

As of the filing date of the present application, the relationship between the reduction of oxidative stress and the protection of liver functions was not clear. As previously discussed, there had been no findings that a reduction of oxidative stress or a prevention of the occurrence of hepatic cirrhosis necessarily prevented an increase in GPT or GOT activity in blood. Instead, an antioxidant which is known to be effective for reduction of oxidative stress causes liver dysfunction (see discussion of Radicut above). Therefore, those skilled in the art could not predict that administration of reduced coenzyme Q₁₀, which was merely known to be effective for the reduction of oxidative stress, would also reduce an increase in GPT or GOT activity in blood. A person having ordinary skill in the art would not have had a reasonable expectation of success if attempting the presently claimed invention.

With respect to Sokol, Sokol discloses a method of preventing and treating liver damage comprising the step of administering a formulation including water soluble Vitamin E, beta carotene and selenium. Sokol teaches that coenzyme Q (ubiquinone) can also be included in the formulation (col. 7, line 66 to col. 8, line 8). However, the reference does not teach that administration of coenzyme Q can reduce an increase in GPT or GOT activity in blood. Further, Sokol does not teach that *reduced* coenzyme Q is included in the formulation.

Tao (U.S. Patent Application Publication No. 2003/0044474) discloses an oral dosage composition comprising a high molecular weight, lipophilic bioactive agent, a lipid matrix, and a polyphenol. Ubiquinone or ubiquinol can be used as the bioactive agent (See Paragraph No. [0076] of Tao). However, Tao does not teach the effect of ubiquinone or ubiquinol on liver functions. Tao merely teaches that polyphenolic compounds can increase the absorption of the bioactive agent when they are simultaneously administered from a triglyceride matrix (See Paragraph No. [0020] of Tao). Accordingly, Tao does not remedy the deficiencies in WO '968 and Sokol.

The Office Action also cited Koike et al. (U.S. Application Publication No. 2002/0142089), which discloses oil compositions. However, the composition does not contain reduced coenzyme Q. Instead, the reference merely teaches that specific oil compositions have effects such as facilitating combustion of body fat and improving liver functions.

Thus, neither Sokol, Tao, nor Koike teaches or discloses a relationship between reduced coenzyme Q and liver functions or GPT or GOT activity in blood. The references fail to remedy the deficiencies of WO '968, and thus fail to render obvious the presently claimed invention. In view of this failure, Applicant respectfully requests the reconsideration and withdrawal of this § 103 rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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